

Atty's Docket: Beiersdorf 754- kgb

SN 10/021,217

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9. (New) The preparation of claim 3 being in a form selected from the group consisting of gels, creams, and lotions.

**CONDITIONAL PETITION FOR EXTENSION OF TIME**

If any extension of time for this response is required, Applicants request that this be considered a petition therefore. Please charge the required fee to Deposit Account No. 14-1263.

**ADDITIONAL FEES**

Please charge any further insufficiency of fees, or credit any excess to Deposit Account No. 14-1263.

**REMARKS**

Claims 1-8 are pending the application. New claim 9 is added.

Claims 1-8 were held rejected as allegedly being obvious in view of WO 99/37282, to von der Fecht, et al., the English language equivalent of which is US 6, 503, 518 B1.

**Von der Fecht's Disclosed Genus of Antioxidants Cannot Support an Obviousness Rejection**

Examiner's rejection appears to be based solely on the recitation of lipoic acid as a suitable antioxidant for use with partially neutralized esters of mono- or di-glycerides and fatty acids and citric acid. US '518, col. 4, lines 51-53. Examiner apparently believes that the specific disclosure of lipoic acid as one of hundreds of named compounds or classes of compounds and derivatives thereof, provides sufficient motivation to suggest the claimed combination.

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It is respectfully suggested that case law and PTO guidelines do not support that this disclosure is sufficient to provide such motivation or suggestion. Accordingly, the rejection under § 103(a) should be withdrawn.

The principle of *In re Baird* is relevant to this matter. *Baird* cautions against finding a specific claimed combination obvious, when it is merely suggested by a reference's shotgun disclosure of the entire art. The entirety of the reference(s) must suggest the claimed combination. *In re Baird*, 29 USPQ2d 1550, 1552 (Fed. Clr.1994); cited at, MPEP § 2144.08. Thus, as in *von der Fecht*, merely listing a component compound, without more, is not sufficient to establish a *prima facie* case of obviousness.

Further, *Baird* indicates that von der Fecht's large number of antioxidants disclosed in the reference does not constitute sufficient suggestion for specifically selecting lipoic acid for the claimed composition against a background of hundreds of antioxidants, including express preferences for Vitamins A, B and derivatives thereof. Therefore, *Baird* supports withdrawing the instant rejection predicated on US '518's disclosure of lipoic acid as one out of hundreds of potential antioxidants.

Applicants suggest that the number of antioxidants disclosed in the US '518 reference is likely to encompass at least several hundreds of different antioxidants. This group is numerically very large. In addition, the diverse structural scope of the disclosed antioxidant groups would not suggest to persons of ordinary skill that all the disclosed antioxidants are interchangeable equivalents, absent clear evidence to the contrary. See Biocraft, infra.

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For exampl , c nsider th generic groups (col. 4. lln 57 to col. 6, lln 32), e.g., amino acids, imldazoles, peptldes, carotenes, carotenoids,  $\alpha$ -hydroxyacids, chelating agents, thiols, and derivatives thereof, sulfoxamlnes, fatty acids, unsaturated fatty acids, zinc and zinc derivatives, mannose and derivatives, etc. These groups encompass several hundreds, if not thousands of antioxidants. In addition, there are many other sub-generic groups as well as specific derivatives disclosed.

Addtlonal support for this proposition is found in *Biocraft*. See, *Merck & Co., Inc., v. Biocraft Laboratories, Inc.*, 10 USPQ2d 1844 (Fed. Cir. 1989). In this case, *Biocraft* sought to invalidate Merck's '430 patent covering a combination of potassium-conserving diuretics under § 103(a). *Biocraft's* position was that the claimed diuretic composition was obvious over the earlier generic disclosure in Merck's '813 patent.<sup>4</sup> *Id.*

The court held that the '813 patent indeed rendered the '430's claimed combination obvious even though the claimed combination was only one in 1200 disclosed combinations. *Id.* at 1845-46. However, the major factor militating toward a holding of obvlousness was that the '813 patented included test results demonstrating synergism between the claimed diuretics. Therefore, the court stated that "[a]s is apparent, 'success' is not dependent upon random variation of numerous parameters....the '813 patent instructs the artisan that any of the 1200 disclosed combinations will produce a diuretic formulation with desirable sodium and potasslum eliminating properties." *Id.* (Emphasis added).

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<sup>4</sup> The district court held that the '813 only rendered the '430's combination obvious to try. *Biocraft* was appealing this holding, which the CAFC reversed.

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In other words, when a reference presents a very large number of possible combinations to the public, the mere disclosure of one against, without more, is not sufficient for a finding that a specific combination encompassed therein, is obvious.

With respect to the instant rejection, the von der Fecht reference provides virtually thousands of combinations based on the broad disclosure of antioxidants. But also critical is the fact that there is no teaching or suggestion of the desirability of specifically using lipoic acid over any other antioxidant.

In fact, von der Fecht clearly states that antioxidants are unnecessary in using its composition. Specifically, von der Fecht discloses that antioxidants are "favourable but which are *nevertheless optional*." See col. 4, lines 54-55. Disclosing that antioxidants are optional components is a long way from the '813's evidentiary showing of obviousness in *Biocraft*. Thus, wherein the '813 reference specifically provided evidence of potent synergy of all the combinations, von der Fecht merely provides a list of optional components.

It is apparent from the court's opinion that had Merck's '813 patent merely listed the diuretic compounds, it would have affirmed the district court's holding of nonobviousness because the disclosure would have merely reached the level of "obvious to try." It is respectfully suggested that in view of *Baird* and *Biocraft*, the instant rejection also constitutes *obvious to try*, which is not sufficient to maintain a rejection under § 103(a). See e.g., *Gillette Co. v. S.C. Johnson & Son, Inc.*, 16 USPQ2d 1923 (Fed. Cir. 1990) ("We have consistently held that 'obvious to try' is not to be equated with obviousness under 35 USC § 103(a).").

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Applicants respectfully suggest that the rejection may be properly withdrawn in view of the foregoing analysis

Von der Fecht Discloses a Clear Preference For Distinct Antioxidants

To establish a *prima facie* case of obviousness in a genus-species chemical composition situation, it is essential that Examiner find some motivation or suggestion to make the claimed invention in light of the prior art teachings. See, e.g., *In re Brouwer*, 37 USPQ2d 1663, 1666 (Fed. Cir.1996). As discussed above, merely naming a compound within a very large group of possibilities does not provide sufficient motivation or suggestion.

*Baird* further indicated that if a prior art reference expressly discloses preferences for specific compounds, this may be taken as an apparent teaching away from the non-preferred compounds. *In re Baird*, 29 USPQ2d at 1552 (Emphasis added). In this context, it is also noteworthy that von der Fecht expressly discloses that the "[p]referred antioxidants are Vitamin E and derivatives thereof and Vitamin A and derivatives thereof." Col. 5, lines 40-41.

Applying *Baird*, the disclosed preference for Vitamins A and E as antioxidants is strong evidence against the lack of motivation make the claimed combination in view of the von der Fecht's disclosure. This is because the reference's disclosed preferences would tend to lead one with skill in the art away from selecting any antioxidant other than Vitamins A and/or E, and derivatives thereof.

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### CONCLUSION

In sum, in order for one of ordinary skill to have extracted the suggestion to make the claimed combination from von der Fecht, the artisan would have had to:

1. Ignore the fact that, antioxidants in general were only optional components, and, not necessary suitable for the claimed purpose;
2. Ignore von der Fecht's expressed preference for Vitamins A and E, and derivatives thereof, as antioxidants; and then
3. Randomly choose lipoic acid from among the hundreds of antioxidant species that von der Fecht discloses.

Applicants respectfully request that the rejection be withdrawn. Examiner has not provided sufficient evidence or line of reasoning to suggest how US '518 would motivate persons of ordinary skill to make the specifically claimed lipoic-acid containing combination. Such evidence or reasoning must necessarily set out why persons in the art would not have preferred one or more of the other hundreds of other antioxidants and derivatives thereof, disclosed in the reference, and specifically Vitamins A or E. Such an explanation has not been provided.

Further, the foregoing remarks provide evidence from case law and the MPEP that merely naming of a compound within a genus is not sufficient to maintain a rejection under § 103(a).

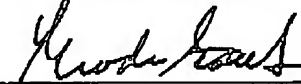
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In addition, th r ferenc expr ssly discloses pr f rences that would further lead  
one with skill in the art away from selecting any antioxidant other than Vitamins A and/or  
E, and derivatives thereof.

In accordance, the rejection should be withdrawn, and the claims allowed.

Respectfully Submitted,

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